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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/553,969	WALLACE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19,21,24-27,30-32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,19,21,24-27,30-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/09;1/28/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response to restriction requirement dated 6-18-10 and IDS dated 12-29-09 and 1-29-10 is acknowledged.

Claims 2-18, 20, 22-23, 28-29 and 33 have been canceled.

Claims 1, 19, 21, 24-27, 30-32 and 34-36 are pending.

Election/Restrictions

Upon careful consideration, the following election requirement made in the previous action has been withdrawn:

A. non-biological polymer - applicants are required to elect a single species of a non-biological polymer from the species disclosed in the instant description.

B. A polysaccharide- applicants are required to elect a single species of a polysaccharide from the species disclosed in the instant description.

However, the requirement to elect a single "protein" (cross-linked as well as non-cross-linked) has been maintained.

In response to the election requirement, applicants elected "gelatin" for the cross-linked as well as non-cross-linked protein without traverse. Applicant's election of gelatin in the reply filed on 6-18-10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 19, 21, 24-27, 30-32 and 34-36 have been examined.

The following new rejection replaces all the rejections made previously of record and applies to claims 1, 19, 21, 24-27, 30-32 and 34-36:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 19, 21, 24, 29, 31-32, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5931165 to Reich et al, and further in view of any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10).

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Wittwer et al teach conditioned water-swellable hydrocolloids for use in mechanical forming processes such as processes such as die molding or injection molding in preparing shaped articles (abstract, col. 10 and col. 2, L 66 through col. 3, l 13). Wittwer teaches a number of polymers such as protein or non-biological polymers for preparing swellable hydrocolloids including gelatin (col. 2, L 37-57). Example in col. 4 describes the preparation of gelating preparation, where in gelatin is conditioned or hydrated to 15% water content and the gelating granules. Further, Wittwer teaches that gelatin is in a granulated form with a mean particle diameter of 0.2 to 4 mm. (claim 6). With respect to the degradation claimed, the property of degradation is associated with gelatin. Wittwer does not teach the hydrocolloid in an applicator but suggests that the

granulated gelatin is coupled with a molding unit such as an injection molding machine and therefore the claimed hydrogel being in an applicator with an extrusion orifice so as to be able to inject gelatin hydrocolloid would have been within the scope of a skilled artisan. Even though Wittwer fails to exemplify other swellable polymers, it would have been obvious for a skilled artisan to choose a biological polymer such as protein or a non-biological polymer or a synthetic polymer to prepare swellable hydrocolloids because Wittwer suggests that the process of preparing a swellable hydrocolloids of predetermined water content, that are suitable for preparing moldable or shaped articles can also be prepared with synthetic polymers.

Wittwer does not teach a combination of cross-linked gelatin and non-crosslinked gelatin, required by the instant independent claims. Wittwer also fails to teach a combination of crosslinked gelatin and a non-biological polymer (for instant claims 31-32 and 36).

Reich et al teach gelatin films for use in the immobilization of tissues comprising cross-linked and non-crosslinked gelatin films and a plasticizer (abstract). Reich teaches that the cross-linked films provide enhanced tensile strength, handling characteristics and resistance to degradation in the surgical environment. Further, Reich states that the films may be crosslinked or non-crosslinked and suggests that the cross-linking should not be to the extent that the ability of the films to fuse with the underlying tissue is diminished (col. 6, L44-54). Reich also teaches including plasticizers such as polyethylene glycol in the gelatin films for tissue immobilization. The plasticizer, polyethylene glycol, of Reich reads on the instant claimed non-biological polymer.

JP 969 teaches preparation of gelatin carriers for immobilized enzymes in which an enzyme is present in the reinforced gelatin gel and the gel is further covered with a crosslinked gelatin gel. JP 969 states that the preparation thus made protects the enzyme activities in the non-crosslinked gel by crosslinking the shell.

JP publication No. 6-254148 (according to the description given the translation) teaches the combination of crosslinked and non-crosslinked gelatin for hemostatic application.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include not only cross-linked gelatin but also non-crosslinked gelatin in the conditioned gelatin hydrocolloid composition of Wittwer and further include polyethylene glycol (PEG) in the composition of because Reich teaches the advantages of having crosslinked as well as non crosslinked gelatin i.e., tensile strength, resistance to degradation and also expect that the presence of some non-crosslinked gelatin would prevent the ability of the films to fuse with the underlying tissue is diminished. JP 969 suggests protecting the substances such as enzymes present in the gelatin gel by crosslinking the top gelatin shell and JP publication No. 6-254148 notes that it is common to use both types in hemostatic applications. A skilled artisan would have also expected the composition of Wittwer to be more pliable by addition of PEG. While the references do not recite the ratio of the cross-linked to the non-crosslinked gelatin, a skilled artisan would have determined the amounts of the same based on the amount of cross-linking desired and at the same time to allow the ability to immobilize the underlying tissues to which the composition is applied. For the

claim limitation, that cross-linked gelatin provides voids in which the non-crosslinked gelatin is present, while Reich does not teach the arrangement; a skilled artisan would expect both the types of gelatins to be admixed that results in the claimed arrangement.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5931165 to Reich et al, and any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10), as applied to claims 1, 19, 21, 24, 29, 31-32, 34 and 36 above, and further in view of US 4,124,705 to Rothman et al and US 4,515,637 to Cioca.

Wittwer teaches gelatin or synthetic polymers that swellable and also suitable for injection molding to prepare shaped articles. Wittwer teaches natural and synthetic polymers are suitable for the preparation of injectable hydrocolloids, but fails to teach an active agent (claim 25) such as a clotting agent (claim 26) or thrombin.

Rothman et al (hereafter Rothman) discloses an agent for intravascular administration consisting of a suspension of minute particles of a polysaccharide that is blocks the finer blood vessels (abstract, lines bridging col. 1-2 and paragraph bridging col. 11-col. 12). The polysaccharide of Rothman is biodegradable and resorbable because Rothman describes that the hydrophilic swellable particles are broken down by alpha-amylase in the blood plasma (col. 2, l 4-16) and further, according to the instant

claim 35, the ability to be resorbable is inherent to the polysaccharide of Rothman. Similarly, the ability to swell is a property inherent to the polysaccharides described by Rothman. Rothman teaches a size range of 0.1 to 300 microns (col. 5, L 18-36), which overlaps with the claimed range of 0.01 mm to 5 mm (10 microns-5000 microns). Rothman further describes that the polymeric gel particles are produced by disintegrating the larger pieces of gel, which reads on fragmented gel claimed in the instant (col. 8, L 3-14). With respect to the limitations of "single phase" and "substantially free form a free aqueous phase", Rothman does not teach including any other substance or component in the polysaccharide suspension other than for the formation of the gel or the ability to form a gel, and also states that the gels contain more than 50% by weight water but less than 98%water (col. 4, L 58-70), which implies that the gels do not contain any free water. Rothman discloses that the particulate suspension is injected intravascularly (col. 8, L 31-48), in conjunction with a therapeutic (col. 9, L 25-34) or a diagnostic agent (col. 8, L 49 through col. 9, L 24). Further the particulate suspension containing polysaccharide particles (of Rothman) is a single phase aqueous polysaccharide. The therapeutic or diagnostic agents of Rothman read on instant claim 25 and particularly mention coagulation factors of claim 26 (col. 9, line 28-30). Rothman fails to teach the specific clotting agent, thrombin of claim 27, but teaches inclusion of clotting agents in the swellable gels for affecting coagulation.

Cioca teaches thrombin as an effective clotting factor for stoppage of bleeding locally (col. 2). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use swellable hydrocolloids of

Wittwer containing gelatin polymer and non-crosslinked gelatin (JP references or Reich) for delivering active agents such as coagulating factors to the desired site because Rothman suggests swellable hydrogels for delivering therapeutic agents such as coagulating agents. Further, it would have been obvious for a skilled artisan to include thrombin as a coagulation factor in the hydrogel composition of Wittwer with an expectation of achieving the desired clotting or coagulation.

Claim 30, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5931165 to Reich et al, and any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10), as applied to claims 1, 19, 21, 24, 29, 31-32, 34 and 36 above, and further in view of US 4,124,705 to Rothman et al and US 6,129,761 to Hubbell .

Alternatively, Claims 30, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5931165 to Reich et al, and any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10), as applied to claims 1, 19, 21, 24, 29, 31-32, 34 and 36 above, and further in view of US 6,129,761 to Hubbell .

Claim 30 now includes protein and polysaccharides. Thus, the scope of the claim 30 with respect to aqueous colloid is similar to that of claim 35. Hence, claim 30 is rejected under the same statute as that of claim 35.

Wittwer teaches gelatin or synthetic polymers that swellable and also suitable for injection molding to prepare shaped articles. Wittwer teaches natural and synthetic polymers are suitable for the preparation of injectable hydrocolloids, but fails to teach the combination of gelatin and polysaccharides.

Rothman, discussed above, teach polysaccharide swellable gels in combination with active agents or hydrocolloids comprising combinations of swellable polymers.

Hubbell teaches injectable hydrogel compositions useful for delivering cells or other bioactive agents via injection and thus provide engraftment and a 3-D template for new cell growth, custom molding of implants as well as implantation of tissues (abstract and col. 5, L 5-23) . The polymers of Hubbell include biodegradable, biocompatible hydrogels such as polylactides, polyanhydrides, polysaccharides and natural polymers such as gelatin, collagen, fibrin etc (col. 7-8), all of which described in the instant. Hubbell also teaches combination or mixtures of polymers (col. 8, L 63 –col. 9, L 12). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to combine other synthetic and natural swellable polymers of Rothman or Hubbell with the polysaccharide swellable polymers of Wittwer for administration because Wittwer suggests that protein as well synthetic polymers are suitable for preparing injection moldable articles, Rothman suggests polysaccharides and Hubbell suggests several swellable hydrogel polymers (both natural polymers such

as gelatin and synthetic polymers) as well as their combinations for administering active agents to the localized or for tissue remodeling or preparing shaped moldable articles. Accordingly, a skilled artisan would have expected to be able to administer active agents or promote tissue engraftment with individual as well as mixtures of hydrogel polymers.

Response to Arguments

Applicant's arguments filed 2-25-10 regarding the teachings of Wittwer, Rothman, Cioca and Hubbell (previously of record) are moot in vie w of the new grounds of rejection.

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

2. JP59-113889 (abstract) teaches immobilization of an enzyme in a water solubelpolymer such as chitosan, polysaccharide and/or protein, and if necessary the surface of the gel is crosslinked.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611